Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

26 MAY 2020

Summary

Substance	Vayego
Application code	APP203605
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	Bayer New Zealand Limited
Purpose of the application	To import for release Vayego into New Zealand for use as an insecticide on various fruit crops
Information requests and time waivers	Further information was requested from the applicant during the evaluation and review of the application in accordance with section 58 of the Act and consequently the consideration was postponed in line with section 59 of the Act
Submissions received	22 submissions were received: Trish Honey Adam Shand Tamara Cartwright John Acres Caroline Barrett Zoe Drayton Reece Baker Tink Stephenson Megan Salole Elliott Young Robyn Phipps David Whyte from Zestos Thomas Burton Nicola Cranfield Emily Davidow Philippa Rawlinson, Policy Advisor, Federated Farmers of New Zealand Larry Burke, New Zealand Salmon Anglers Association Inc.

	Tony Dean, Environment and Conservation Organisations of NZ Inc. Gerry Te Kapa Coates, Ngāi Tahu HSNO Komiti Tim Herman, New Zealand Apples & Pears Incorporated Anthony Bellvé, Waikato Domestic Beekeepers' Association Dr Oksana Borowik, Barry Foster, Dr Mark Goodwin, Don MacLeod, John McKay, Dr John McLean, Apiculture New Zealand Science and Research Focus Group
Considered by	A Decision-Making Committee of the Environmental Protection Authority ("the Committee"): Dr Kerry Laing (Chair) Dr Ngaire Phillips Dr John Taylor
Decision	**Approved with controls**
Approval code	**HSR101424**
Hazard classifications	9.1A, 9.4A

Application dates	
Date application formally received	7 June 2018
Submission period	21 June 2018 – 2 August 2018
Hearing date	30 October 2019, adjourned for the applicant to provide further information
Hearing closed	9 April 2020
Consideration date	9 April 2020 – 26 May 2020
Date decision signed	26 May 2020

1. Application context

Background

1.1. The applicant, Bayer New Zealand Limited, submitted an application on 18 April 2018 to import for release Vayego into New Zealand for use as an insecticide on various crops. It was given the application number APP203605 and was formally received on 7 June 2018 as a notified Category C application.

1.2. Vayego is a suspension concentrate containing 200 g/L of tetraniliprole as the active ingredient.

1.3. Tetraniliprole is a new active ingredient to New Zealand, and at the time of formal receipt, was not approved in Australia, Canada, Europe, Japan or the USA. Tetraniliprole was approved in South Korea.

1.4. Vayego is intended to be used as an insecticide to control codling moths, leaf rollers and other pests in pome fruit, stone fruit and grapes by ground-based application methods.

1.5. The applicant initially applied to have Vayego approved by ground-based and aerial methods on forage brassicas but subsequently withdrew its use on this crop (confirmed on 18 September 2018), therefore, this use pattern was not assessed by the EPA.

1.6. The applicant initially applied to have Vayego approved for use on kiwifruit. Following the hearing adjournment, and the request for further information in the Direction and Minute (issued 21 November 2019), the applicant removed kiwifruit from the Good Agricultural Practice (GAP) table and no longer sought to have kiwifruit included for consideration.

1.7. When applied to pome fruit, the applicant had proposed an application rate of 60 g/ha tetraniliprole (equivalent to 0.3 L/ha Vayego), with a maximum frequency of three applications per year and a minimum interval period of 21 days between applications. The applicant altered the maximum application frequency from three to two per year prior to the hearing held on 30 October 2019.

1.8. When applied to stone fruit, the applicant proposed an application rate of 60 g/ha tetraniliprole (equivalent to 0.3 L/ha Vayego), with a maximum frequency of two applications per year and a minimum interval period of 14 days between applications.

1.9. When applied to grapes, the applicant proposed a maximum application rate of 60 g/ha tetraniliprole (equivalent to 0.3 L/ha Vayego), with a maximum frequency of one application per year.

Hazardous properties

1.10. The classifications applicable to the active ingredient in Vayego, tetraniliprole, were based on toxicological and ecotoxicological studies conducted using the technical grade active ingredient.

1.11. The following classifications were identified for tetraniliprole: 6.1E (inhalation), 6.5B, 9.1A and 9.4A.

1.12. Tetraniliprole is was not considered rapidly degradable under the Act. Tetraniliprole was considered persistent in the aquatic environment and in soil under some conditions but was not considered to be bioaccumulative.

1.13. The classifications applicable to Vayego were based on product data, the composition of the substance, and the properties of its components.

1.14. The following classifications were identified for Vayego: 9.1A and 9.4A.

Process, consultation and notification

1.15. The application was formally received on 7 June 2018 under section 28 of the Act.

Notification to government departments

1.16. The following government departments were notified of the application on 7 June 2018: the Ministry for the Environment, the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries, the Ministry of Health and the Department of Conservation. The Ministry for the Environment provided a comment to state that they will not be recommending to the Minister to call in the application under s68 of the Act. No further comments were received.

1.17. As the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW Act) and the Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations), advice was also sought from WorkSafe New Zealand ("WorkSafe") on whether the HSW requirements were adequate to manage the risks associated with the use of this substance in the workplace. WorkSafe was notified of the application on 7 June 2018 and provided with the appropriate documents to allow them to provide their advice.

1.18. In their response, WorkSafe considered that, "as this substance is only classified as a Class 9, then the Health and Safety at Work (Hazardous Substances) [HSW (HS)] Regulations do not apply". However, it is noted that a number of HSW (HS) requirements are triggered by the ecotoxic properties of Vayego under the EPA Notices and the HSW (General Risk and Workplace Management) Regulations apply.

Public notification

1.19. The application was publicly notified under section 53 of the Act as it was considered likely that there would be significant public interest in the application. This is because Vayego contains a new active ingredient that has not previously been assessed under the Act.

1.20. The application was open for submissions on 21 June 2018 and the consultation period ended on 2 August 2018.

Submissions

1.21. Twenty-two submissions were received on the application.

1.22. Two submissions supported the application. These were from Federated Farmers of New Zealand and New Zealand Apples & Pears Incorporated. Federated Farmers of New Zealand considered having an insecticide with a new mode of action to protect forage brassicas (the crop applied for in the initial application) from pests would be beneficial to farmers, while New Zealand Apples & Pears Incorporated supported the application because they considered having access to selective products that target pest organisms and minimise impacts on non-target organisms would be beneficial for growers.

1.23. Seventeen submissions opposed the application. These were from New Zealand Salmon Anglers Association Inc., Environment and Conservation Organisations of NZ Inc. and members of the public. These submissions highlighted concerns around safety to the environment and the time necessary to gather information about toxicity in real field conditions (with references to other products such as Roundup). Some of these submissions also expressed concern over the side effects on bees, toxicity to the aquatic environment and non-target insects and the development of resistance.

1.24. Three submissions were neutral. These were from Ngāi Tahu HSNO Komiti, Waikato Domestic Beekeepers' Association and Apiculture New Zealand Science and Research Focus Group. These submissions wanted more information provided, including information on the properties, risk assessment and proposed controls for the substance. Some submissions also raised concerns about the lack of consultation with beekeepers and the uncertainties regarding the resistance and toxicity of tetraniliprole and its metabolites to honey bees, moths and birds.

Request for additional information

1.25. After public notification of the application, it was determined that further information regarding the effects of the substance was required. This information was requested on 3 August 2018 under section 58 of the Act and included the request for several toxicological studies and environmental fate data, as well as ecotoxicological study data on bees, earthworms and algae.

1.26. As result of the volume of information received from the applicant that required further evaluation, the consideration period of the application was postponed in line with section 59 of the Act to give the EPA sufficient time to complete their evaluation.

Hearing

1.27. The hearing for Vayego was held in Wellington, New Zealand on 30 October 2019.

1.28. The hearing was held in the presence of the Decision-Making Committee ("the Committee"), the applicant and representatives, the EPA and the submitters who wished to be heard (Apiculture New Zealand Science and Research Focus Group, Ngāi Tahu HSNO Komiti, Plant and Food Research Hawkes Bay, New Zealand Apples & Pears Incorporated and Waikato Domestic Beekeepers' Association).

Information available for consideration

1.29. The information available to the Committee for consideration of this application consisted of the:

- application form, including the confidential material submitted by the applicant;
- associated documents, including toxicological, ecotoxicological and environmental fate studies on tetraniliprole and Vayego;
- submissions;
- information received from WorkSafe;
- hearing presentations made by the applicant, the EPA and submitters;
- EPA Staff Evaluation and Review Report and Science Memorandum.

1.30. After the EPA published the Science Memorandum in September 2019, a draft of which had been previously shared with the applicant on 28 March 2019, additional information was provided to the EPA by the applicant on 18 October 2019. This information was released to all parties to the process on 21 October 2019.

1.31. As the new information was communicated so close to the hearing date, the EPA was unable to assess this new information prior to the hearing. The DMC had considered postponement of the hearing but decided to proceed, as there was little time for parties to change their arrangements for attendance at the hearing.

1.32. The new information provided by the applicant proposed a refinement of the aquatic risk assessment for the spray drift and runoff entry routes, as well as a refinement of the endpoint to be selected for the aquatic risk assessment, changing the toxicity endpoint from a 28 day No Observed Effect Concentration (NOEC), to using the EC_{10} value (Effective Concentration at which an observable adverse effect is caused in 10% of the test organisms) which the applicant considered as more scientifically robust. The applicant also changed the number of applications for pome fruit from three to two per year. These amendments had not been suggested by the applicant previously.

1.33. Upon hearing the applicant's presentation and the significant changes proposed, the DMC decided to adjourn the hearing on 30 October 2019 and a Direction and Minute was issued by the Committee on 21 November 2019, requesting information to be provided to the EPA by 31 January 2020, including a new Good Agricultural Practice (GAP) table that would lay out the uses to be evaluated by the EPA and justification for any deviations to the EPA aquatic risk assessment, including spray drift and runoff risk assessments. Information was also requested to outline the justification and proposed risk mitigation options for any deviations to the EPA's risk assessment on sediment-dwelling organisms, and also for non-target arthropods and pollinators based on a reduced number of Vayego applications (from three to two applications per year). The information requested is described in more detail under section 4.

1.34. Once the information was received from the applicant on 27 January 2020, it was made publicly available on the EPA website, and submitters had 15 working days from 31 January 2020 to submit any comments. No comments were received from submitters.

1.35. The EPA then prepared an addendum to the risk assessment, which was made publicly available on the EPA website on 12 March 2020. Submitters were given 10 working days to comment on the EPA addendum of the risk assessment. Comments were received from the applicant and New Zealand Apples & Pears. The applicant did not raise concerns about the technical points of the risk assessment but suggested changes to the controls. New Zealand Apples & Pears stated that the new proposed buffer zones alongside waterbodies would be workable. Details of these comments can be found under section 4.

1.36. Once the Committee received the information requested in the Direction and Minute, the addendum to the risk assessment from the EPA, and the comments from various parties and submitters, the Committee held a teleconference and concluded that the hearing could be formally closed and a decision process could commence.

Legislative criteria for the application

1.37. The application was considered in accordance with section 29 of the Act, taking into account other relevant sections of the Act, the EPA Notices, the HSW Act and HSW (HS) Regulations and the Hazardous Substances and New Organisms (Methodology) Order 1998.

2. EPA Staff Evaluation and Review Report (Staff Report)

2.1. The Staff Report (dated September 2019) is the EPA review of the application and available information. It provides information to assist the Committee's decision-making process.

2.2. The EPA identified the classifications and properties of the active ingredient, tetraniliprole, in Vayego based on toxicological and ecotoxicological studies conducted with this active ingredient. The EPA then identified the classifications of the substance Vayego, which were based on formulation data, the composition of the substance, and the properties of its components.

2.3. The EPA conducted quantitative human health and environmental risk assessments. These assessments considered the exposure and subsequent effects on people and the environment throughout the life cycle of the substance.

2.4. Based on all the available information, the EPA assessed the potential risks that the substance may pose to the environment, human health, the relationship of Māori to the environment, society, community and to the market economy.

2.5. The EPA also considered whether there were benefits associated with the use of the substance.

2.6. The EPA identified a suite of prescribed controls based on the hazard classifications of Vayego, and considered variations to these controls, including maximum applications rates, number of applications and frequency, and the addition of controls, including large buffer zone controls, in accordance with sections 77 and 77A of the Act.

2.7. The EPA considered that there was sufficient information available to assess the application to import Vayego for release. The EPA considered whether the risks to human health and the environment from the importation and use of Vayego could be mitigated with the proposed controls in place; and that the use of Vayego could provide some benefits to growers. The EPA had some reservations about the substance when applied three times in a calendar year and suggested a label statement warning end-users of the potential negative effects to beneficial insects.

3. The hearing

3.1. The hearing for Vayego was held at the Terrace Conference Centre in Wellington, New Zealand on 30 October 2019.

3.2. On behalf of the applicant, Bayer New Zealand, a joint presentation was given by Sekove Tinalevu, Dr Hans Eerens and Richard Mohan, from Bayer New Zealand, and Robbie McCormick from Mr Apple. Dr Elodie Urlacher and Michael Berardozzi presented on behalf of the EPA. Presentations were also given by submitters on behalf of Apiculture New Zealand Science and Research Focus Group (presented by Don Macleod), Ngāi Tahu HSNO Komiti (presented by Gerry Te Kapa Coates), New Zealand Apples & Pears Incorporated (presented by Rachel Kilmister), Plant and Food Research Hawkes Bay (presented by Dr Jim Walker) and Waikato Domestic Beekeepers' Association (presented by Anthony Bellvé).

Applicant's presentation

3.3. The applicant, began by giving a description of Vayego and its use pattern.

3.4. The applicant introduced the company, Bayer New Zealand, and highlighted that they are making an important contribution to providing a reliable supply of high-quality food, feed and plant-based raw materials.

3.5. The applicant described how it can take up to ten years to bring a new pesticide to the market at a significant cost.

3.6. The applicant noted that the substance had been registered in South Korea and they have pending registrations in other countries such as Canada, USA, Australia and Japan. They are hoping to get registration in Canada and USA by early 2020 [substances containing tetraniliprole have subsequently been approved in Canada as of March 2020].

3.7. The presentation given by the applicant was focused on pome fruits only but the applicant noted that the application also covered stone fruits, grapes and kiwifruit.

3.8. The applicant noted that it had changed the number of applications for pome fruit from three to two per year [the applicant stated that two applications of Vayego were effective for pome fruit].

3.9. The application included stone fruits, grapes and kiwifruit and three applications on pome fruit in order to future-proof against potentially needing to undertake a modified reassessment. Their current application with Agricultural Compounds and Veterinary Medicines (ACVM) is only for pome fruit. While the applicant has undertaken studies on stone fruit, grapes and kiwifruit, these were not considered sufficient to submit to ACVM at the time.

3.10. The applicant highlighted the continual growth of the horticulture export revenue and partially attributed it to the use of innovation and the adoption of new technology. The applicant went on to say that Vayego would be a valuable tool in the "toolbox" to ensure this continual growth.

3.11. Robbie McCormick from Mr Apple was used as an industry representative for the applicant. He described the size of the apple industry, with Mr Apple making up around 25% of New Zealand's apple industry, using about 10% of the planted area of the industry. Mr McCormick also noted that 80% of Mr Apple's products leave New Zealand and the markets they mainly focus on are in Asia, especially China.

3.12. Mr McCormick noted that Asian markets had a zero tolerance for codling moth. He also noted that spraying with Vayego would be targeted and not based on calendar spraying, and he spoke about how the substance will be used in conjunction with integrated pest management (IPM) systems.

3.13. Mr McCormick explained the type of trees that would be typically used by growers. They have developed a smaller tree, the new trees are around 3 m to 3.5 m tall, giving around 777 trees per hectare. The old trees were about 5 m tall [the applicant had argued that the APVMA spray drift scenario that the EPA used in the original Science Memorandum for pome fruit (dense orchard) was

only representative of “tall trees” (more than 5 m). The applicant disputed the fact that the dense orchard scenario was representative because apple trees in NZ were not that high].

3.14. The applicant stated that approving Vayego for use would increase grower choice and could also reduce the numbers of sprays needed.

3.15. The applicant stated that Vayego could target all life stages, was fast-acting and had long lasting effects, and should not leave residues if used in accordance with the label instructions.

3.16. The applicant then presented the risks associated with Vayego. He stated that there were no human health classifications. The applicant stated that the “environmental risks were mostly positive”, with the risk less than the level of concern when used in accordance with label instructions.

3.17. The applicant also mentioned that by only allowing the two applications per year of Vayego on pome fruit there would be no requirement to have IPM label requirements.

3.18. The applicant stated that they disagreed with the aquatic risk assessment and that spray drift data from the Australian Pesticide and Veterinary Medicines Authority (APVMA) using the “dense orchard” scenario [related to canopy density and not tree density] was not reflective of modern apple and pear growing methods in New Zealand, resulting in unnecessarily large buffer zones. The applicant would have preferred that the EPA used the European spray drift data (based on apple tree data) as it is a better match for New Zealand. The applicant noted that this method is also used in Canada and Australia and by the New Zealand EPA [used for non-target arthropods].

3.19. The applicant also noted that the slope the tree crops are grown on will usually be flat. The exception to this would be grapes, especially in Otago region of New Zealand [the slope parameter used in runoff risk assessment was modified from 12.5% to 5.2%, thereby reducing the amount of potential spray runoff and allowing a reduced buffer zone].

3.20. The applicant also spoke about the environmental fate risk assessment of the active ingredient. The EPA assessment considered sorption to sediment but only after the final application. The applicant stated that the active ingredient has a strong tendency to adhere to sediment, reducing the concentration of the active ingredient in the waterbody, which would have an effect on the risk.

3.21. The applicant spoke about waterbody depth. The EPA considered the concentration at the edge of the waterbody and no consideration was given to mixing within the waterbody.

3.22. The applicant proposed an endpoint change from No Observed Effect Concentration (NOEC) to the EC_{10} value (the value that effects 10% of the test organisms) for the aquatic assessment. They considered this a more robust approach to the endpoint for the risk assessment.

3.23. The applicant, concluded their presentation by explaining that the benefits far outweighed the risks.

3.24. The Committee questioned whether the applicant made any comments or commissioned anyone to comment on the risk assessment methodology provided by the EPA [public consultation was run between 6 June 2018 and 6 July 2018]. The applicant stated that Agcarm were to provide comment on

the EPA risk assessment methodology [feedback was provided by both Agcarm and Bayer in July 2018, but not on the points raised during the Vayego application].

3.25. The Committee commented on the increase in productivity in the apple export sector from the data presented by the applicant, and asked what the major factors were that allowed this. Mr McCormick responded by saying orchard practices had an impact on productivity. Trees used to be bigger and taller but now they use dwarfing root stocks, these could be planted closer together and were more productive.

3.26. The Committee asked whether the "toolbox" is working, and if so, why should there be another pesticide added to it. Mr McCormick answered by stating that it is always good to have more tools, and that they have lost some in the past due to resistance. They also utilise a "stacking" approach, using multiple pesticides and not relying on one pesticide.

3.27. The Committee then asked what "tools" were currently being utilised and which of these could compliment Vayego. Mr McCormick responded by giving two examples of other substances and noted that there were not a lot of tools in the toolbox. The Committee then asked whether these other insecticides were of a separate chemical classification to Vayego. The applicant responded by saying one of the substances was in the same class but there was also the potential for "diamide stacking" which could attack the insect at different stages of its lifecycle.

3.28. The Committee then asked whether resistance to diamide insecticides has been seen. Jim Walker from Plant and Food Research Hawkes Bay answered by saying that they had not seen any resistance to the diamide group. Mr Walker went on to say that they have seen resistance to tebufenozide substances and that high use in some orchards has led to resistance.

3.29. The Committee asked how much of a problem codling moth was. Mr Walker answered by saying it was the number one pest issue for Asian markets, with the risk of market closure. The Committee then asked, as the risks already exist, whether there was an increase in risk that would require more "tools". Mr Walker answered by saying that because of the current systems in place, New Zealand has a high level of freedom from codling moth, however, there had been previous failure with the tebufenozide product and this could risk a loss of efficacy and future access to export markets.

3.30. The Committee asked whether Vayego could replace tebufenozide. Mr Walker said Vayego could replace or support tebufenozide products.

3.31. The Committee then asked how orchardists were currently dealing with resistance. Mr Walker answered by saying there is an insecticide-resistance plan and growers are reminded to use a mixed chemistry approach. The Committee asked if Vayego is as good as it is purported to be then what will stop users solely using this substance. The applicant responded by stating they had trials using Vayego with another substance, with results showing better results using these two substances than Vayego alone.

3.32. The Committee asked what was meant by effects on arthropods being transient and reversible, as mentioned in the application, the applicant answered this saying, at a collective level, the population will survive but the substance may have an effect on a few individual organisms.

3.33. The Committee also asked why the applicant thought an EC_{10} value was more appropriate to use than NOEC. The applicant answered that NOEC uses an arbitrary value that the researcher has selected at the beginning of a test, whereas an EC_{10} value can show some effects. EC_{10} value is now accepted in Europe for aquatic risk assessments. The Committee responded by saying that it did not consider the NOEC as being arbitrary as it still shows a point of effect, relating to the way the test is set up, and asked whether a loss of 10% of the population was acceptable. The applicant answered by saying it was acceptable based on the data.

3.34. The Committee asked the applicant to elaborate on what was meant by the low costs to Vayego. The applicant commented that the low cost of Vayego was relative to the cost of the damage that would occur if the insects got through [into the market], not the costs compared to other similar products. It was based on a return on investment.

3.35. The Committee asked for clarification on what proportion of apple orchards practice IPM. Mr Walker answered by saying all of the export orchards carry out integrated fruit production which is a comprehensive form of IPM. The industry is heavily reliant on biological control.

3.36. Gerry Te Kapa Coates from Ngāi Tahu HSNO Komiti asked the applicant what proportion of orchards in New Zealand had moved from “dense” to “European” style growing systems. Mr McCormick responded by saying around 90 to 95% will be using a dwarfing root stock, with anything that had been planted in the last 20 to 25 years using a dwarfing root stock. Mr Coates followed up by asking Mr. McCormick to clarify whether there were still dense orchards [in New Zealand]. Mr McCormick stated that there will be dense orchards, due to the life span of the trees.

3.37. Mr Coates asked the applicant about spray runoff. Mr McCormick answered by saying they are targeting their spraying to match the canopy density, any runoff is wasted product and therefore, wasted money.

3.38. Mr Coates expressed concerns about reduction of the overall chemical burden from a new product. The applicant answered by saying that Vayego should replace some of the older chemistry being used and it could potentially target more insect pests, thereby reducing the number of chemicals needed in the spray tank to be applied onto the orchards but it depends on how it is adapted and adopted for use by the growers.

3.39. Mr Coates enquired about IPM and if [beneficial] insects will need to be re-introduced after the use of Vayego. The applicant gave one specific example of a parasitoid that attacks woolly apple aphid which was not affected by the use of Vayego. The applicant further stated that Bayer had undertaken studies in Germany showing Vayego had a low impact on beneficial insects, with some individual insects being lost but not entire populations.

3.40. Stephanie Dykstra from Ngāi Tahu HSNO Komiti enquired about Vayego's effect on species of Lepidoptera, other than codling moth. The applicant replied saying it was effective against diamond back moth and white butterfly but they were only looking at specific crops for the development of Vayego, therefore, they would not be looking at developing Vaeygo for use for these other species. Ms Dykstra then asked if testing occurred using native species. The applicant responded by saying testing was carried out using the standard OECD test guidelines and that they thought the product was compatible with IPM.

3.41. Ms Dykstra asked why the applicant thought the spray drift analysis should include the entire waterbody instead of its leading edge as most invertebrate species they [the Ngāi Tahu HSNO Komiti] are interested in protecting are found on the leading edge. The applicant responded by saying that they wanted to factor in waterbody depth for the runoff calculation as it had not been considered by the EPA. The applicant went on to say that every other regulator in the world would consider this.

3.42. Mr Coates asked for confirmation regarding the treatment of brassica with Vayego. The applicant confirmed that they were not intending to register Vayego for use on brassica.

3.43. Don Macleod from Apiculture New Zealand Science and Research Focus Group ("Apiculture New Zealand") asked whether the mode of action of Vayego was as a toxic insecticide, an anti-growth regulator or an anti-feedant and what were the sub-lethal effects. The applicant responded by saying that Vayego's mode of action was as an anti-feedant and has some physiological effect on the development of the target insect. The applicant stated that they had not undertaken studies in New Zealand on the sub-lethal effects of Vayego.

3.44. Mr Macleod then referred to a trial on broadcast spraying on *Phacelia* [*tanacetifolia*] in the EPA Science Memo (Table 227, page 474), discussing brood termination rates as being three times higher in the treatment group than the control group, and that the conclusion stated no major effect was observed in the behaviour, mortality, flight intensity and colony strength of the bees but a transient effect on brood development was apparent. Mr Macleod wanted confirmation on what was meant by "transient effect". Dr Elodie Urlacher from the EPA answered by stating that the general conclusion was based on adult bees and that there was a small decline in the number of brood due to mortality [the absolute number of dead brood was low], for a period of time after the Vayego treatment, that would then recover, with no major effects on adults. Mr Macleod then outlined why these numbers would have a significant effect on a bee hive. The applicant then responded by saying the study referred to by Mr Macleod was based on Vayego being applied before flowering and that their label will be stating that Vayego will not be applied pre-flowering, always post-flowering.

3.45. Mr Macleod asked whether *Phacelia* [*tanacetifolia*], an annual plant, was an appropriate surrogate plant for kiwifruit (a perennial, vine plant). The applicant reiterated that Vayego will not be applied to pre-flowering plants and this was a standard test used around the world and there would be controls set by the EPA, based on the hazard classifications, on not allowing the substance to be applied to plants that are in flower.

3.46. Anthony Bellvé from the Waikato Domestic Beekeepers' Association made a general statement regarding the research on the action of tetraniliprole on cell types. Mr Bellvé expands on this in his presentation.

EPA's presentation

3.47. Dr Elodie Urlacher presented the EPA assessment, starting with an announcement that the presentation would mainly focus on part of the assessment that needed refinement. The statement was made that the EPA would not be presenting everything on the EPA Staff Advice report, only briefly touching on the human health assessment but that they would be presenting on the aquatic risk assessment. There was no presentation on the cultural assessment but the EPA had a member of staff present to answer any questions pertaining to the cultural risk assessment.

3.48. The EPA gave a brief description of the substance, Vayego, and provided some background on the application timeline.

3.49. The EPA also stated that they supplied the applicant with the Science Memorandum in March (2019) and requested feedback. The applicant provided additional studies for non-target arthropods, a refinement of the aquatic risk assessment, and requested a change to the use pattern to two applications on pome fruit and to remove the application pre-bloom on kiwifruit. The EPA incorporated some of the new information into the Science Memorandum, published in September 2019. The applicant submitted further information on additional refinement of the aquatic risk assessment on 18 October 2019.

3.50. The hazardous properties and some characteristics of tetraniliprole were presented. Tetraniliprole was classified as 6.1E (inhalation), 6.5B, 9.1A and 9.4A. Tetraniliprole was not considered rapidly biodegradable and was considered persistent in soil and aquatic environments, however, it was not considered to be bioaccumulative. In addition, tetraniliprole was also considered to be very mobile in soil.

3.51. The EPA also presented the hazard classifications of Vayego as 9.1A and 9.4A, and then described the use pattern, application rates and frequencies for various fruit types for which Vayego would be applied to.

3.52. The EPA gave a high level summary of the human health risk assessment. Vayego had no classification for human health. The Acceptable Operator Exposure Limit (AOEL) was derived by toxicologists which was used for the risk assessment, calculating tetraniliprole at 0.88 mg/kg bw/day. Using the AOEL and modelling data, the EPA concluded that risk to operators, re-entry workers and bystanders were all below the level of concern. The human health risk assessment was shared with WorkSafe who did not raise any concerns for human health.

3.53. The environmental risk assessment was presented, as well as the quantitative risk assessment and methodology used. The EPA found risks to groundwater, earthworms and soil organisms, non-target plants and birds were all below the level of concern. Soil accumulation risk, taking into account a

repeated application over 20 years, was also below the level of concern. However, for aquatic organisms, pollinators and non-target arthropods further modelling and refinement was needed.

3.54. Michael Berardozzi from the EPA then presented the aquatic risk assessment and how the buffer zones were determined. The EPA spoke about the extensive data package submitted by the applicant that included acute and chronic endpoint derivation. The EPA retained the chronic NOEC endpoint value of 0.0008 mg/L for tetraniliprole for the most sensitive species from the data provided by the applicant for the aquatic risk assessment. The EPA noted that the EC_{10} value discussed by the applicant did not come out of the study report and was not provided in the application when it was lodged in 2018 nor when the EPA shared the Science Memorandum with the applicant in March 2019. Therefore, the NOEC endpoint value selected by the EPA was considered the worst-case scenario and retained for use in the assessment.

3.55. The EPA discussed how they derived the aquatic buffer zones for Vayego, using spray drift curves (established by the Australian Pesticides and Veterinary Medicines Authority (APVMA)) for an airblast application scenario. The EPA also selected the “dense orchard” scenario, which is not the most conservative scenario (the “sparse orchard” gives a higher proportion of spray drift), but was considered the most relevant scenario. Spray drift curves were averaged to take into account the differences in dimensions of waterbodies that may be affected by spray drift. The buffer zone for Vayego was determined to be 200 m [for pome fruit] when using the chronic endpoint value. The EPA acknowledged that this was high and may not be practical but were determined following the EPA’s standard approach.

3.56. The EPA also stated that they were unable to review the new information provided by the applicant (submitted on 18 October 2019) in its entirety before the hearing.

3.57. Dr Urlacher from the EPA then presented on the pollinator risk assessment. The EPA stated that the Risk Quotient (RQ) values were above the level of concern for bees, which was typical for an insecticide. Due to these risks, a refinement of the risk assessment was conducted using residue data provided by the applicant which showed that tetraniliprole could be systemic, meaning it could be detected in different parts of the plant, including pollen.

3.58. The EPA stated that no residue data was provided for grapes, but as the flowers of this crop were considered to have a low attractiveness to bees, as well as the time of application being post-bloom, the risks were considered negligible. Pollen residue data was provided by the applicant for pome fruit and stone fruit, with risks estimated to be below the level of concern by the EPA.

3.59. The EPA stated that no residue data was provided for the application of Vayego on kiwifruit. The applicant initially proposed a pre-bloom application of the substance, and as such, it was estimated that residues could still be present in the flowers when bees would visit the crops. The EPA modelled the worst-case scenario using the data available to see what would be the highest residue level needed to achieve an adverse effect on bees. It was estimated that the level required in pollen was a lot higher than the maximum level detected in other crops. Therefore, it was concluded that the risk of

application on kiwifruit was unlikely to be above the level of concern. As such, no additional controls were proposed as there were already prescribed controls to prevent the application on flowering crops.

3.60. Michael Berardozzi from the EPA then presented on risks to non-target arthropods, stating that there were two types of arthropods the EPA looks at: the in-field, beneficial arthropods, used in IPM, which are present inside the treated area; and off-field, non-target arthropods, present outside of the treated area that might be exposed to the substance by way of spray drift and other mechanisms.

3.61. The EPA stated that based on the information provided for in-field risks, it concluded that risks above the level of concern were identified, therefore, a more refined approach was needed. The applicant submitted semi-field studies which showed that for one or two applications, at 60 g tetraniliprole/ha, effects were observed as being potentially slightly harmful but concluded that it would still be compatible with IPM. For three applications, there was insufficient data to determine whether it would be compatible with IPM. Therefore, an additional control would be proposed to warn users on IPM compatibility for three applications.

3.62. For off-field risks, the EPA determined that, for non-target arthropods outside of the treated area, for one application, risks were considered acceptable. For two or three applications, the EPA determined that the field study generated did not adequately cover this scenario and after several applications there could be some effects on non-target arthropods. Therefore, an additional control was proposed to alert users to the risks of spray drift to non-target arthropods outside of the treated area when two or more applications are proposed.

3.63. The EPA then presented on the prescribed controls based on the hazard classifications of Vayego and the recommended variations and additions to those controls under sections 77 and 77A of the Act. Tolerable Exposure Limits (TELs) were not proposed for Vayego.

3.64. Acceptable Daily Exposure (ADE) and Potential Daily Exposure (PDE) values were provided. The additional controls included a maximum application rate of 60 g tetraniliprole/ha, a maximum frequency of three applications per year, application method restrictions (only ground-based methods permitted and favourable wind conditions), buffer zones and additional label warnings (to protect non-target arthropods and to warn that three applications is not compatible with IPM).

3.65. Environmental Exposure Limits (EELs) were not proposed for Vayego.

3.66. The EPA then presented the benefits of Vayego as described by the applicant. It was acknowledged by the applicant that Vayego would provide more choice for growers and that because the substance contains a new active ingredient, this was considered a significant benefit. The applicant also claimed that the substance could be used in an IPM programme, however, the EPA had reservations about this, particularly with three applications. It was also acknowledged that the substance had good efficacy. While the EPA considered that having an efficacious substance is a significant benefit, efficacy data is assessed by ACVM, therefore, the level of benefit could not be assessed by the EPA.

3.67. The applicant stated that the product was a good tool to manage resistance. Again, this is assessed by ACVM, however, the EPA acknowledged that there was concern from submitters regarding the family of the active ingredient [diamide family]. The applicant also stated that Vayego would be used at lower application rates than other diamide substances, the EPA disputed this. If applied three times per year, Vayego would not have an overall lower application rate. The EPA also pointed out that an application rate was not indicative of toxicity, therefore, it may not have been relevant in this case.

3.68. The applicant stated that their substance had excellent crop safety, however the EPA could not assess this as it is evaluated by ACVM. Finally, the applicant claimed that Vayego would generate revenue for growers. The EPA acknowledged that by having a new product this may provide beneficial effect to some businesses.

3.69. The EPA concluded their presentation by stating there was sufficient information to assess the application. With controls in place, the risks to human health were negligible, and the risks to the environment could be mitigated, however, with three applications, the proposed controls could limit the use of the substance.

3.70. The EPA also stated that, although not covered in the presentation, the conclusion of the cultural risk assessment did not highlight any significant adverse effect on the ability of Māori to maintain their economic, social, and cultural well-being.

3.71. The EPA concluded that Vayego would provide some benefits to growers.

3.72. The Committee asked the EPA why it did not use the EC_{10} value and instead used the NOEC value. The EPA responded by stating that they followed the standard approach when conducting the risk assessment, which they considered conservative but also realistic and the most appropriate for the data they had received. The EPA also reiterated that they had shared the buffer zone information with the applicant in the Science Memorandum [in March 2019] with the purpose of receiving more refined endpoints, however, the applicant did not comment on these at the time.

3.73. The Committee asked about the spray drift curves and averaging data across the waterbodies. The EPA responded by stating that the spray drift curves represented the proportion of the drift that could reach a waterbody, however, it had not taken into account the dimension of the waterbody. The EPA further stated that they took into account the dilution element of the substance reaching a particular waterbody and that, historically, the EPA had taken into account a 30 cm deep and 50 m wide waterbody in its evaluation.

3.74. The Committee asked about the recommendation of a warning on the substance for non-target arthropods and about the compatibility with IPM. The EPA stated that there was a warning for compatibility for three applications but for two applications there was only a recommendation to minimise spray drift. The EPA added that they looked at two areas of the risk assessment, in-field and off-field, and that these recommendations were related to the off-field risk assessment, which was separate from the IPM compatibility discussion. The EPA further stated that the threshold and the protection goal associated with in-field and off-field arthropods were different. For in-field, the EPA

concluded that there was some effect on insects but that it would not wipe out the entire population, therefore, it would not affect the ability for the IPM to be functional.

3.75. The Committee asked about Vayego's mobility in soil. The EPA responded by stating that this was determined by soil absorption studies which look at whether the substance adheres to the soil particles or the water phase in soil. For Vayego, it had a preference to be found in the water phase, giving a low partition coefficient value, meaning the substance has a propensity to move into the soil column, potentially reaching groundwater. This was taken into account during the EPA's assessment.

3.76. The Committee asked about the impurities of tetraniliprole and whether they were reviewed as part of the assessment. The EPA responded by saying they had reviewed the impurity information and found that the active ingredient did not contain any impurities of toxicological or ecotoxicological concern.

3.77. The Committee enquired about the "sparse-orchard" modelling. The EPA responded by saying they looked at the worst-case scenario for drift proportion. The Committee then asked about whether the modelling factored in the direction of spray (ie up against the trees). The EPA responded by saying it took into account whether there would be upwards movement, downwards movement or between-rows movement depending on the morphology of the trees.

3.78. The applicant made a comment about the fairness of the EPA's standard risk assessment methodology given that they submitted what they considered a large amount of data. The EPA responded by stating the process that they followed was laid out by the HSNO Act and they had taken into consideration all of the data submitted.

3.79. Gerry Te Kapa Coates from Ngāi Tahu HSNO Komiti asked about buffer zones, in particular, discussing the downwind measurement for spray drift. The EPA stated they make wind speed recommendations as part of the conditions of use.

3.80. Mr Coates also asked about the airblast sprayer applying the substance to the last row of crops, and whether the direction of spray would be on the land side or water side. The EPA responded by reiterating what had been previously mentioned by one of the submitters, that any wasted substance would mean wasted money.

3.81. Mr Coates asked about non-target plant risks and the aquatic toxicity. The EPA responded by stating there was no significant toxicity on non-target plants, algae and other aquatic plants based on the data supplied by the applicant, and that a risk assessment was conducted for this based on the proposed use pattern.

3.82. Don Macleod from Apiculture New Zealand enquired about the persistence of Vayego in plants and soil and why it was not considered bioaccumulative. The EPA discussed the differences between bioaccumulation and persistence and how they took both of these into consideration in their assessments.

3.83. Anthony Bellvé from the Waikato Domestic Beekeepers' Association commented that bees like the periphery of crops and asked whether that was taken into consideration. The EPA responded by

stating that they took a tiered approach to assessing the risks, where Tier 1 modelling looked at the worst-case scenario, eg spraying the substance directly onto a bee or the bee feeding solely on crops with high levels of residues, which Vayego failed, meaning that the EPA then looked at Tier 2. The second tier used residue data from crops intentionally sprayed with Vayego. Tier 2 was considered worse than spray drift from outside the area. Because the risk using the Tier 2 modelling was considered acceptable, the spray drift concentration was assumed to be a lower risk.

3.84. Mr Bellvé stated that tetraniliprole was either a systemic or semi-systemic compound that could penetrate cells, and asked, based on this, whether the uptake of tetraniliprole had been studied in nectar or pollen. The EPA responded by stating that the residue data that was provided by the applicant included some of the bee studies. These studies measured tetraniliprole in pollen and nectar and they mostly concluded that it was below the level of detection or quantification in nectar, however, there were data for residues in pollen that was taken into account during the EPA's bee risk assessment.

Presentations by submitters

Apiculture New Zealand

3.85. Don Macleod from Apiculture New Zealand gave a general presentation on Apiculture New Zealand, the members and their purpose. Mr Macleod stated that Apiculture New Zealand agreed with the EPA Staff Report that the substance was toxic to bees.

3.86. Mr Macleod expressed concern over the number of changes to the application, with new data received from the applicant [on 18 October 2019] prior to the hearing, stating that brassicas, as a target crop, would be withdrawn and the application of the substance had changed from three applications to two. He also stated that the change in application on kiwifruit, from pre-flowering spray to post-flower spray was not known to Apiculture New Zealand prior to the hearing. Mr Macleod was also concerned about the lack of a safety data sheet (SDS) and draft label with the application.

3.87. Mr Macleod spoke about the active ingredient being systemic and persistent in the plant and expressed concerns about it appearing in pollen. He also stated that Apiculture New Zealand agrees with the applicant that the fruit trees and kiwifruit vines do not grow to 20 metres in height.

3.88. Mr Macleod raised concerns over the persistence of the active ingredient up to ten months after spray has occurred. He went on to explain the uses of pollen in the lifecycle of honeybees, particularly as part of a food source for honeybee larvae, reiterating his previous comment on the transient effect on brood. He stated that if the brood has been terminated in the first few days of the lifecycle due to the use of the substance, it will put the entire cycle back around 25 to 26 days, which had flow-on effects to growers and their crops. Mr Macleod also reiterated the lack of appropriate surrogate plant for kiwifruit data.

3.89. Apiculture New Zealand support no spraying during flowering.

3.90. The Committee asked whether Apiculture New Zealand was opposed to any systemic pesticides being used that may end up in pollen, irrespective of the concentration of the substance. Mr Macleod responded by stating they were very cautious around the risks to bees gathering pollen and nectar and potential effects on international trade. They would be interested in the mechanism of how the pesticide would enter the pollen and nectar, and whether use restrictions could minimise the risk. Mr Macleod gave an example, saying that he was comfortable hearing Bayer stating they would only spray post petal-fall.

3.91. The Committee enquired about petal-fall and what confidence did they have that bees would not be at risk during this time. Mr Macleod answered by stating that petal-fall happens reasonably quickly and there could be a chance of a late bee visit but that this was unlikely.

Ngāi Tahu HSNO Komiti

3.92. Gerry Te Kapa Coates from Ngāi Tahu HSNO Komiti began his presentation by giving an overview of Ngāi Tahu, the area they cover, or have mana whenua over, their values and the issues they consider. Mr Coates expressed concern over the lack of culturally relevant information and the effects on native species, although he conceded that the applicant consulted Ngāi Tahu 18 months prior to the hearing. Mr Coates stated that the EPA do “active protection, not just passive acceptance of the facts”.

3.93. Mr Coates also mentioned the new data presented [on 18 October 2019] prior to the hearing and stated that although they were initially neutral on the introduction of Vayego [into New Zealand], they decided to oppose the application on further reflection and following the release of the Science Memorandum.

3.94. Mr Coates expressed concern over the lack of knowledge on the full composition of Vayego and that no draft label had been provided. He also mentioned that Vayego was only approved in South Korea and felt nervous that approval for this substance was lacking in other jurisdictions.

3.95. Mr Coates expressed concern regarding risks related to spray drift and runoff into adjoining water courses, as well as the risks to non-target plants.

3.96. Mr Coates noted that it seemed as though Vayego would be added on to the existing range of tools and it would not affect the overall chemical burden.

3.97. Mr Coates summarised his presentation by reiterating the concerns over spray drift and runoff and risks of aquatic contamination.

3.98. The Committee asked Mr Coates to explain what elements of the recent data provided by the applicant caused the Ngāi Tahu HSNO Komiti to change its stance on Vayego. Mr Coates responded by saying the process of getting the new information was the issue.

3.99. Julian Jackson from the EPA commented on Ngāi Tahu as usually being the only submitters on these types of applications and further stated that it was something the EPA had concerns about, however, the EPA was aware that this was often due to groups being under resourced, as well as funding

issues. Mr Coates responded by stating that "just because Māori say nothing, does not mean they have nothing to say".

3.100. The applicant commented that Ngāi Tahu had a horticultural arm and asked whether it was consulted as well. Mr Coates responded by saying the horticultural arm of Ngāi Tahu was not consulted on the change in stance by the Ngāi Tahu HSNO Komiti. Mr Coates went on to say they have had no complaints on their approach. Stephanie Dykstra from the Ngāi Tahu HSNO Komiti clarified this further by stating that they work from an approved policy document, therefore the views of the Ngāi Tahu HSNO Komiti are the views all Ngāi Tahu, including the horticultural and agricultural arms of their tribe.

3.101. Anthony Bellvé from the Waikato Domestic Beekeepers' Association asked whether Ngāi Tahu had large apiaries. Mr Coates responded by saying Ngāi Tahu had bought a honey firm.

New Zealand Apples & Pears

3.102. Rachel Kilmister from New Zealand Apples & Pears began her presentation with an overview of their industry, including the export market, and stated that New Zealand was ranked the number one industry in the world for the last four years according to the Belrose's 'International Competitiveness Rankings' and outlined what contributed to that ranking, including the productivity of New Zealand's orchards. Ms Kilmister also stated that the industry has gone from using trees that were around six metres in height to a higher density system that include dwarfing root stocks to increase productivity.

3.103. Ms Kilmister noted that the industry was increasingly moving towards the use of trees which created more fruit on the outside of the tree as opposed to the larger trees where fruit was hidden under the leaves. This created better quality apples, with more exposure to light accessing the trees. Ms Kilmister also spoke about the "2D systems" which created a wall of fruit on the outside [of the tree], and therefore, increased productivity.

3.104. Ms Kilmister spoke about how New Zealand is known for its low-residue fruit production and also noted the food safety assurance system used by the industry.

3.105. Ms Kilmister then presented on the phytosanitary risk management process, particularly for the management of codling moth. She stated that they must follow a Ministry for Primary Industries (MPI) assurance programme to ensure the risk of codling moth is managed for the key export markets. Ms Kilmister also noted that the assurance programme followed a systems approach which is based on IPM, such that it contains a number of control points, and application of chemicals was only carried out when there was justification to do so.

3.106. Ms Kilmister concluded the presentation by stating that the codling moth-sensitive export markets of China, Taiwan, Japan and Australia were important for the industry and discussed the market value for those countries.

Plant & Food Research

3.107. In a joint presentation, Dr Jim Walker from Plant and Food Hawkes Bay followed on from Ms Kilmister from New Zealand Apples & Pears to present on an overview of the Integrated Fruit Production (IFP)

programme which is an expanded version of IPM. Dr Walker emphasised the importance of being residue-free for the European market and pest-free for the Asian market.

3.108. Dr Walker highlighted the changes being made to modern intensive orchards. These orchards can have “up to 2000 trees per hectare” (previously orchards had around 700 tree per hectare), with a reduced canopy height, a reduction in insecticide applications and a reduction in water spray volumes being used, while increasing productivity.

3.109. Dr Walker gave an overview of the Integrated Fruit Production (IFP) programme. The programme looked to maximise the use of biological controls whilst eliminating the use of organophosphate insecticides that had been traditionally used in the apple industry and to replace these with “soft” and selective pest management systems.

3.110. Dr Walker discussed the effects of the IFP and that because of this programme, the hazard classifications 6.1A and 6.1B had been eliminated from the industry as they have been using “soft” pesticides. Dr Walker presented data that was gathered from growers’ spray diaries, collected nationally. Dr Walker also highlighted that the US EPA had found that, due to the low levels of residues on New Zealand apples, the risk posed by them were only slightly higher than organic apples.

3.111. Dr Walker also mentioned the efficacy of Vayego against other insects such as bronze beetle and the apple leafcurling midge. Dr Walker stated that defence against the woolly apple aphid was entirely reliant on biocontrol methods and that the beneficial parasitoid, *Aphelinus mali*, was a highly sensitive species. Vayego was found to be safe to use in the presence of this parasitoid. Dr Walker also stated that there had been no new insecticides registered in the apple industry for around 15 years.

3.112. The Committee commented on one of the graphs in Dr Walker’s presentation, asking whether the use of pesticides had increased since 2015, after having declined since the 1990’s, as a result of an increased production. Dr Walker responded by stating that the graph would likely be updated in 2020. Dr Walker further pointed out that the graph took into account the total pesticide use on a per hectare basis. He also mentioned that pesticide use will increase in proportion to the increase in the area of production. The key point Dr Walker wanted to make was that the pesticide use per hectare had dramatically fallen by 90 percent since the 1990s.

3.113. The Committee commented that the apple industry could claim that it was almost organic and asked what the difference was between the yields of organic growers compared to that of growers using IFP and what do organic growers use to achieve their yields. Dr Walker responded by emphasising that they did not claim to be organic. Dr Walker also mentioned that organic growers do not have the same productivity, in some cases this can have a reduction of up to 15 to 20 percent for Royal Gala apples and it could be halved for Braeburn when compared to growers using the IFP.

3.114. The Committee noted that codling moth had a virus used as a biocontrol method and asked whether this was used in the industry. Dr Walker responded, saying that it was used in the apple industry and was a critical part of the industry achieving the low residue profile.

3.115. The Committee, referring to one of the graphs in Dr Walker's presentation, asked why the use of biological pesticides appeared to have a bit of variability. Dr Walker answered, stating that variability was caused in part by the introduction of pheromone-based mating-disruption technology which is not considered a biological pesticide.

3.116. The Committee asked for clarification of how the IPM system works in an open environment. Dr Walker answered by stating that orchards are rich, biodiverse places, with natural colonisation of insects occurring. If the system was working as it should then there would be no need to introduce additional beneficial species into orchards.

3.117. The Committee asked what would happen to the apple and pear industry if Vayego could not be utilised. Dr Walker said that this would lead to a weaker export market and would put MPI's phytosanitary export certification under stress. The Committee commented that the industry appears to have undergone phenomenal growth without the introduction of any new insecticides since around 2005. Dr Walker responded by stating that if the industry wants to access or expand into markets they would need more focus on field control solutions as they cannot rely on methyl bromide fumigation [on harvested crops].

3.118. The Committee asked what proportion of the apple industry was not exported. Dr Walker replied stating that a high proportion was exported, around 68 percent.

3.119. The applicant commented that while the industry looks to be thriving, this is creating pressure on the current products being used on multiple generations of pests. Dr Walker responded by stating that New Zealand gets one generation of codling moth a year (this is not always the case in some other countries). Dr Walker also stated that they have a comprehensive resistance management programme but had already lost some [insecticide] products due to resistance, and that Vayego would add to that resistance programme and could potentially remove another product that is only used to control bronze beetle.

3.120. The EPA asked a question regarding the assessment of the effects on parasitoid wasps. Dr Walker discussed the bioassay method used. The EPA also asked Dr Walker whether he had any comments on the controls suggested by the EPA. Dr Walker suggested that the buffer zones would not be workable for most orchards and also questioned some of the assumptions regarding downstream drift.

3.121. The EPA also asked about insects varying from orchard to orchard and whether tests were conducted for compatibility. Dr Walker stated those sorts of trials would be routinely conducted by Bayer, and to some degree Plant and Food Research, and the merchant suppliers have their own research and evaluation programmes.

Waikato Domestic Beekeepers' Association

3.122. Anthony Bellvé presented on the biochemistry of tetraniliprole, highlighting the variations in structure of tetraniliprole, and how this active ingredient works.

3.123. Mr Bellvé highlighted two similar products to tetraniliprole (chlorantraniliprole and cyantraniliprole), which were both used as pesticides for a number of years and both had caused some resistance due to the receptor changing in the amino acid sequence.

3.124. Mr Bellvé then went on to discuss why he would consider tetraniliprole as being systemic. Mr Bellvé stated that tetraniliprole, like other diamide pesticides, will enter an animal cell and bind to particular receptors within that cell that are responsible for regulating the release of calcium. As a result, the calcium channels would get locked half open, allowing calcium to rush out, causing cell death.

3.125. Mr Bellvé concluded his presentation by highlighting his concerns with the dose and mortality rates from the data provided by the applicant, and stressed the point that bees are extremely sensitive.

3.126. The Committee asked about the literature Mr Bellvé referred to when discussing the resistance of chlorantraniliprole and cyantraniliprole and asked if the mutation causing resistance was common between them. Mr Bellvé responded by saying he thought they were different mutations but had not read those particular papers.

3.127. Gerry Te Kapa Coates from Ngāi Tahu HSNO Komiti asked Mr Bellvé to sum up his presentation. Mr Bellvé responded by stating that tetraniliprole was very toxic to honey bees and bumble bees, and both of these insects play an important role in productivity. He went on to say that he believed there would be ways to apply tetraniliprole that would not affect honey bees.

Applicant's right of reply

3.128. Regarding the comment from one of the submitters about the residue in pollen ten months after application, the applicant emphasised that the EPA had thoroughly assessed the data presented by the applicant and had concluded that the risk was considered acceptable.

3.129. Regarding the comment from one of the submitters stating that Vayego could be a replacement product to another, more hazardous substance used in the industry, the applicant felt it supported the use of Vayego.

3.130. Regarding the risk assessment undertaken, the applicant stated that in future they would be looking at carrying out these well before making an initial submission of a new substance.

3.131. The applicant stated that because of the new data submitted by them prior to the hearing, they understood that the hearing may need to be adjourned in order for the new information to be assessed in full.

4. Consideration

4.1. Following the hearing, the Committee decided that the new information and the proposed change to the use pattern provided by the applicant to the EPA on 18 October 2019 would need to be evaluated by the EPA. To enable time for this to occur, the Committee adjourned the hearing.

4.2. The Committee directed the applicant to provide the following to the EPA by 31 January 2020 for assessment, under a Direction and Minute, issued on 21 November 2020:

- a new Good Agricultural Practice (GAP) table, laying out the uses to be evaluated by the EPA;
- a full justification of endpoints to be selected for the aquatic risk assessment for all susceptible organisms. This was to cover both the acute and chronic endpoints where relevant;
- a risk assessment for the aquatic environment for entries **via spray drift** using the EPA methodology and full justification for potential deviations (different spray scenarios and drift curves for instance) for all considered uses. This was to include a proposal of risk mitigation options as required;
- a risk assessment for the aquatic environment for entries **via runoff** using the EPA methodology and full justification for potential deviations (different slope values for instance) for all considered uses. This was to include a proposal of risk mitigation options as required;
- a risk assessment for the aquatic environment for **sediment-dwelling organisms** using the EPA methodology and full justification for potential deviations. This was to include a proposal of risk mitigation options as required;
- a risk assessment for non-target arthropods based on the reduced number of applications where relevant. This was to include an in-field and off-field risk assessment. Justification for non-relevance should have also been provided, as well as a proposal of risk mitigation options as required;
- a risk assessment for pollinators based on the reduced number of applications where relevant. Justification for non-relevance was to be provided, as well as a proposal of risk mitigation options as required.

4.3. Once the information was received from the applicant (on 27January 2020), it was made publicly available on the EPA website (on 31 January 2020), and submitters had until 24 February 2020 to submit any comments.

4.4. The EPA then prepared an addendum to the risk assessment, including a full evaluation of the documents provided by the applicant, which was made publicly available on the EPA website (12 March 2020). At this point, submitters had 10 working days to provide any comments.

4.5. The addendum to the risk assessment concluded that:

- The applicant had removed kiwifruit from the new GAP table and no longer sought kiwifruit be included for consideration;
- For non-target arthropods, the EPA considered that one or two applications of Vayego would not result in unacceptable effects to organisms used in Integrated Pest Management and therefore recommended **not** to apply the following label statement that was initially advised to

be applied: "**WARNING**" the substance might not be not compatible with Integrated Pest Management (IPM) when applied three times. For non-target arthropods off-field, the following label statement was still required: "The best available application technique, which minimises off-target drift should be used to reduce effects on non-target insects or other arthropods".

- For pollinators, no new information was received from the applicant. Therefore, the conclusion of the EPA and the applicant remained the same: the risks for grapes, pome fruit and stone fruit were below the level of concern;
- For the aquatic risk assessment endpoint, the applicant proposed that an EC_{10} was more appropriate than the NOEC value. The EPA considered that the applicant had not provided a case as to whether the use of an EC_{10} in the aquatic risk assessment would result in the same level of protection as when using a NOEC. The EPA acknowledged that the use of an EC_x value could be beneficial due to the limitations of the NOEC. However, within the New Zealand EPA methodology, the respective value of x, as well as the corresponding safety factor to ensure the same level of protection is achieved, had not been established. As such, the EPA did not recommend the use of an EC_{10} for the risk assessment at this point in time but agreed that it would be prudent to carefully explore this option and change the methodology, if needed, in the future.
- For the sediment risk assessment endpoint, the EPA did not consider it necessary to recalculate the NOEC into an EC_{10}. If the buffer zones recommended by the EPA in the refined spray-drift and runoff risk assessment were applied, the sediment dwelling organisms would be protected.
- For the spray drift assessment, the EPA agreed with some of the arguments presented by the applicant and incorporated some of these aspects in the spray drift risk assessment. The changes that were made related to the application frequency (two applications instead of three), exclusion of environmental fate parameters (sorption) in the assessment, and the calculation of the Multiple Application Factor (MAF) using the DT_{50} in the water column. The Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) curves were used to determine the downwind buffer zone up to 50 m.
- Results of the EPA refined risk assessment are presented in Table 4 of the addendum to the risk assessment, the EPA concludes that downwind buffer zones of 10 to 25 m, depending on the application method, frequency and interval, are required to protect the aquatic environment (initially, the EPA had buffer zones of up to 200 m).
- For the runoff risk assessment, the EPA incorporated some aspects suggested by the applicant and recommended to refine the MAF to 1.93. The EPA did not recommend considering the concentration to be homogenously distributed in the waterbody. For the slope analysis, the EPA suggested a refinement of the slope to 5.2%. A refined risk assessment

carried out by the EPA indicated that a 15 m runoff buffer zone was required (originally, the EPA had calculated a 20 to 25 m buffer zone).

4.6. The revised buffer zones proposed for Vayego are as follows (Table 1):

Table 1: Revised buffer zones proposed for Vayego

Application method	Sensitive area	Previously proposed buffer zones (m)	Revised required buffer zones (m)
Ground-based Pome fruit	Waterbody	25	25
	Waterbody (downwind)	200	25
Ground-based Stone fruit	Waterbody	20	25
	Waterbody (downwind)	140	25
Ground-based Grapes and kiwifruit*	Waterbody	20	20
	Waterbody (downwind)	5	10

*Kiwifruit was subsequently removed from the GAP table submitted by the applicant on 27 January 2020.

4.7. On 19 March 2020, the applicant submitted a response to the addendum to the risk assessment. The applicant did not raise concerns about the technical points of the assessment, however they suggested changes to the controls. The applicant had concerns regarding the wording of the controls in the previous Staff Report (published September 2019). In particular, both the application rate control and the buffer zone control were linked to the intended crop not the application rate and application method. The applicant's preference was to set the maximum application rate independently of the crop, and to link the buffer zone control to the application method.

4.8. On 19 March 2020, New Zealand Apples & Pears submitted a response to the addendum to the risk assessment and stated that a 25 m buffer zone alongside waterbodies would be workable and allow the product to be used effectively in the majority of orchard blocks, while protecting waterbodies. New Zealand Apple and Pears further stated that the revised controls are realistic and achievable with industry best practice requirements for responsible agrichemical applications to pipfruit.

4.9. The Committee considered the new information provided by the applicant, the EPA assessment of the new information, and the new comments from submitters in order to make their final decision on the Vayego application.

4.10. The application was considered by the Committee on 9 April 2020 via teleconference, following the decision pathway (available in Appendix B).

4.11. The following information was considered by the Committee:

- the application form and its confidential appendices, including toxicological, ecotoxicological and environmental fate studies on tetraniliprole and Vayego;
- the submissions;
- the Science Memorandum;

- the Staff Report;
- the WorkSafe assessment report;
- the Cultural Risk Assessment;
- information presented at the hearing;
- new information as directed in the Direction and Minute issued by the Committee, including new information from the applicant, an addendum to the risk assessment from the EPA, and new comments from the submitters.

4.12. The Committee considered that it had received sufficient information to proceed with its consideration of the application. Further comments on different aspects of this information can be found in the following sections.

5. Hazardous properties of Vayego

5.1. The hazard classifications of Vayego, shown on Table 2, were determined by the EPA using studies on the formulation provided by the applicant, information on the individual components of Vayego and by mixture rules.

5.2. The classifications that have been applied to Vayego are different to those submitted by the applicant. This is because tetraniliprole is not classified as being toxic to target organs as the Lowest Observable Adverse Effect Level (LOAEL) exceeds the threshold for classification.

Table 2: Hazard classifications of Vayego

Hazard	Applicant classification	EPA classification
Target organ or systemic toxicity (oral/dermal/inhalation)	**6.9B**	**ND***
Aquatic ecotoxicity	9.1A	9.1A
Terrestrial invertebrate ecotoxicity	9.4A	9.4A

*ND not determined. There are no data for some of the co-formulants, therefore the classification is ND.

6. Risk and benefit assessment

Risk assessment

6.1. The Committee took into account the EPA risk assessment for Vayego as detailed in the Science Memorandum and the addendum to the risk assessment (dated 5 March 2020). The key points are summarised below.

6.2. The risk assessments took into account the full life cycle of the substance, including import, packaging, transport, storage, use and disposal.

6.3. The EPA determined that there was potential for significant exposure to people and the environment during the use phase of Vayego. Therefore, a quantitative assessment was undertaken to determine the likely exposure routes to the substance under the use conditions proposed by the applicant. The use patterns considered are for airblast application on pome fruit, stone fruit and grapes.

6.4. The overall risk and benefit assessment:

- considered the risks posed by Vayego;
- determined whether the risks outweighed the benefits;
- determined whether any variations or additions to the prescribed controls were required to manage the risks of the substance, and identified controls that may not be applicable or necessary that could, therefore, be deleted.

Risks during importation, manufacture, transportation, storage and disposal

6.5. The applicant intends to import Vayego, packaged and ready for sale. The risks associated with the importation, manufacture, transportation, storage and disposal of Vayego were considered by the Committee based on the EPA risk assessment.

6.6. The Committee considered that compliance with the proposed controls and other legislative requirements would ensure that the level of risk to human health and the environment from importation, manufacture, transportation, storage and disposal of Vayego would be negligible. These requirements include the considerations in Part 2 of the Act, the Hazardous Substances Notices regarding packaging, identification, emergency management and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's HSW requirements.

Assessment of risks to human health

6.7. The risks from the use of tetraniliprole on users, operators of the substance, re-entry workers and bystanders was considered a proxy for Vayego.

6.8. The Committee noted that the quantitative risk assessment determined that risks to operators during the mixing, loading and application of Vayego by a ground-based airblast sprayer was negligible, even without the use of PPE.

6.9. The Committee acknowledged that the re-entry risks to persons entering the treated area and undertaking activities such as searching, reaching and picking fruits were below the level of concern even if no PPE was worn. The estimated risks to bystanders was also below the level of concern and no buffer zones were proposed to mitigate risks to human health.

6.10. The Committee acknowledged that WorkSafe assessed the available information for Vayego and, in their response, considered that "as this substance is only classified as a Class 9, then the Health and Safety at Work (Hazardous Substances) [HSW (HS)] Regulations do not apply". However, it is noted

that a number of HSW (HS) requirements are triggered by the ecotoxic properties of Vayego under the EPA Notices and the HSW (General Risk and Workplace Management) Regulations apply.

6.11. The Committee acknowledged that there were no impurities of toxicological concern.

6.12. The Committee considered that the risks to human health from the proposed use of Vayego were acceptable. There was no need for the application of a re-entry interval (REI) or an additional buffer zone to protect bystanders.

Assessment of risks to the environment

6.13. The risks to a range of environmental receptors from the use of tetraniliprole was considered a proxy for the risks from Vayego.

6.14. The potential risks posed by Vayego to aquatic and terrestrial environments were assessed for the specific use patterns proposed by the applicant. The Committee noted that the EPA evaluated these use patterns and performed quantitative modelling to determine the predicted environmental exposures.

6.15. The Committee noted that tetraniliprole is considered highly persistent in the aquatic environment and persistent in soil. The Committee also noted that tetraniliprole is considered highly mobile in soil, however, it is not considered bioaccumulative.

Aquatic environment

6.16. The Committee acknowledged that the EPA assessment found that the risks to the aquatic environment from the proposed use of Vayego were above the level of concern. To mitigate the risk, additional controls (eg buffer zones and maximum application rates) to reduce spray-drift and runoff would be necessary.

6.17. The Committee noted that the applicant and the submitters from Plant and Food Research were concerned about the size of the buffer zones proposed by the EPA in the Science Memorandum, while submitters from Ngāi Tahu HSNO Komiti were concerned about the spray drift. However, the Committee also noted that the EPA produced an addendum to their initial risk assessment based on additional information submitted by the applicant both prior to and after the hearing (on 18 October 2019 and 27 January 2020, respectively). The resulting risk assessment was considered appropriate by the Committee.

6.18. The Committee agreed with the methodology that assessed risk to the aquatic environment proposed by the EPA in the addendum to the risk assessment, and in particular, the use of NOEC as the appropriate endpoint value. Therefore, the Committee agreed with the required buffer zone controls proposed by the EPA as outlined in the addendum to the risk assessment.

6.19. The Committee agreed with the EPA's recommendation to restrict the amount of Vayego to be applied per hectare, and the number and frequency of applications per year. The Committee also agreed with

the EPA's recommendations to restrict the application of Vayego to favourable wind conditions and to restrict the application of the substance to ground-based methods only.

Groundwater

6.20. The Committee acknowledged that the EPA assessment found risks to groundwater contamination were below the level of concern.

Sediment

6.21. The Committee noted that the EPA assessment found the risk quotient of tetraniliprole was above the level of concern at the first tier of analysis. However, it was considered that the controls proposed to protect the aquatic environment, in particular, buffer zones reducing the risk from spray drift and runoff, would also protect the sediment-dwelling organisms and reduce risks to a negligible level. As such, no additional controls were proposed for sediment-dwelling organisms.

Soil organisms

6.22. The Committee noted that the EPA assessment found that the predicted acute exposures of tetraniliprole to soil were below the level of concern for earthworms and soil micro-organisms. The Committee also noted that no chronic data for the active ingredient was provided, however, chronic data for the substance was provided for earthworms and soil mites.

6.23. The Committee acknowledged that the results from the EPA assessment, which included the chronic studies, indicated that the risks were below the level of concern. Furthermore, the potential for soil accumulation following three applications per year (worst-case scenario initially submitted by the applicant) of Vayego was evaluated (over a 20 year period) and no risks to soil organisms were identified.

Non-target plants

6.24. The Committee noted that the EPA assessment found that non-target plant exposures to tetraniliprole, when applied to fruit crops and grapes as the formulated product Vayego, were below the level of concern for both threatened and non-threatened species when applied at higher than proposed application rate (200 g ai/ha instead of 60 g ai/ha). As such, the risk to non-target plants is considered negligible and no additional controls were deemed necessary.

Birds

6.25. The Committee noted that the EPA assessment found that risks to birds were below the level of level of concern when using Vayego. The Committee also noted that as tetraniliprole is not bioaccumulative, there was no need to conduct a risk assessment for secondary poisoning for this active ingredient.

Pollinators

6.26. The Committee noted that the EPA required a tiered risk assessment in order to assess the risks to pollinators, and found that a Tier I (worst-case scenario) assessment indicated a risk above the level

of concern, therefore, further refinement was necessary. In Tier II, pollen residue information was used to refine the risk assessment for pome and stone fruit, and the risks were determined to be below the level of concern.

6.27. The Committee also noted that no residue analysis was provided for grapes, but given the low attractiveness of flowering grapes to bees, the risks were considered negligible.

6.28. The Committee acknowledged that no information on the residues in kiwifruit was available, however, considering the maximum residues found and the minimum residue level required to trigger an effect, these risks are also considered to be below the level of concern. Also, the applicant has advised that they are no longer pursuing consideration for kiwifruit.

6.29. The Committee also acknowledged the concerns of the submitters from Apiculture New Zealand and Waikato Domestic Beekeepers' Association on the effects on bees. In particular, they acknowledged Apiculture New Zealand further expressing their concerns about persistence of tetraniliprole and its appearance in pollen and the Waikato Domestic Beekeepers' Association expressing their concerns over "the systemic or semi-systemic" nature of tetraniliprole.

Non-target arthropods

6.30. The Committee noted that the EPA required a tiered approach to assess risks to non-target arthropods. Risks were evaluated in-field on beneficial arthropods, used in IPM, and off-field for non-target arthropods.

6.31. The Committee noted that the EPA re-evaluated the risks to non-target arthropods following the provision of new information from the applicant, the results of which are outlined in the addendum to the risk assessment document.

6.32. The initial risk assessment was performed up to Tier III as a result of the risks identified for the pome fruit scenario, for which the maximum number of applications was initially three. The maximum number of applications to pome fruit has been reduced to two applications in the revised GAP table. At Tier II, as well as when evaluating additional information in Tier III, it was concluded that for one or two applications, no unacceptable effects in-field would be observed for beneficial arthropods. Therefore, the Committee concluded that one or two applications of Vayego would not result in unacceptable effects to organisms used in IPM.

6.33. The Committee noted that when considering a weight of evidence approach, for two applications instead of three, off-field effects were likely to be limited but could not be fully excluded. Therefore, they agreed with the EPA approach that it would be best practice to include the following label statement:

- "The best available application technique, which minimises off-target drift, should be used to reduce effects on non-target insects or other arthropods."

Assessment of risks to Māori and their relationship to the environment

6.34. The Committee noted that the EPA assessed the potential effects on the relationship of Māori to the environment in accordance with sections 5(b), 6(d) and 8 of the Act. This included an assessment of the potential impacts of Vayego on kaitiakitanga, and fulfilment of Treaty of Waitangi obligations.

6.35. Based on the Staff Report and the addendum to the risk assessment, and other information provided to the Committee by the applicant and submitters, the Committee considered that with the proposed controls in place, the impact of approval of use of Vayego on the relationship of Māori with the environment would be negligible, and likely to be consistent with the principles of the Treaty of Waitangi.

Assessment of risks to society, the community and the market economy

6.36. The Committee considered that the overall risks to society, the community and the market economy from the approval of Vayego would be negligible provided the controls are met.

New Zealand's international obligations

6.37. The Committee noted that no international obligations that may have been impacted by the approval of Vayego have been identified.

Assessment of benefits

6.38. The applicant referred to several benefits of Vayego in their application and elaborated on these at the hearing. The EPA also provided some information to support some of these claims.

More choice for growers

6.39. The applicant considered that the approval of Vayego would give more choice for growers in regards to control of codling moth, leaf roller species and noctuid that affect important horticultural crops such as pome fruit, stone fruit, kiwifruit and grape, which have a high export value. The applicant stated that Vayego controls quarantine pests in important export markets such as China, Japan, Taiwan, South Korea and the EU. The EPA noted that Vayego contains a new active ingredient which could provide for an additional tool for growers, therefore this was considered a **significant benefit**.

6.40. The EPA noted that for crops such as pome fruit, stone fruit and grape, there were currently 16 registered products to combat codling moths (relying on eight active ingredients, none of them diamides), 68 for leaf rollers (relying on 17 active ingredients, two products with chlorantraniliprole) and only one for noctuid moths (relying on one, non-diamide active ingredient). The EPA noted that no other single product covered all the same uses proposed for Vayego.

Use in Integrated Pest Management (IPM)

6.41. The applicant stated that Vayego had very good physiological selectivity and low effects on a wide range of very different and important groups of biological control agents including predatory mites such as *Amblyseius swirskii* and *Typhlodromus pyri*, parasitoids such as *Aphelinus mali* and *Encarsia*

formosa, predatory bugs such as *Cyrtorrhinus lividipenis*, as well as spiders, earwigs, hoverflies and ladybird beetles. They claim that Vayego could thus be safely used in IPM strategies.

6.42. The applicant also provided an evaluation regarding the compatibility of Vayego with IPM at lower application rates and/or lower application frequencies. Based on the assessment and associated provided studies, it was concluded that the risks from a single application at 60 g ai/ha was considered likely to be below the level of concern for predatory bugs (eg. *Orius spp*), earwigs (*Forficula sp*) and ladybirds (*Coccinellidae*). For two applications, less information was available, however, based on the data provided and the maximum observed effect, it was possible to conclude that the substance is slightly harmful. The EPA considered this acceptable, but considered that it should also be evaluated by the end-user on a case-by-case basis.

6.43. Therefore, this benefit was not fully supported by the evidence. The EPA instead proposed a label warning to advise users to minimise spray drift to limit off-field effects for two applications.

Efficacy

6.44. The applicant considered that the approval of Vayego would provide a reliable control of a broad-spectrum of economically important *Coleopteran*, *Dipteran*, and *Lepidopteran* pests. They stated that Vayego had activity against all stages of pests: eggs, larvae, pupae and adults and that it induced immediate cessation of insect feeding which would prevent crop damage on low economic threshold vegetable and fruit crops.

6.45. The efficacy of Vayego will be assessed by ACVM, as such, the EPA had no information on which to assess this benefit. The EPA noted however that an efficacious substance would be a significant benefit.

Resistance

6.46. The applicant claimed that Vayego, and its active ingredient tetraniliprole, was an effective diamide with no known cross-resistance to other Insecticide Resistance Action Committee (IRAC) Groups; and that it could control pests resistant to insecticides with other modes of action, including carbamate, organophosphate, pyrethroid and spinosyn insecticides. They considered Vayego would be an effective rotation option for managing pest species such as the diamond back moth which has shown some resistance to classes of insecticides such as pyrethroids.

6.47. New Zealand Apples & Pears Incorporated supported this benefit.

6.48. Environment and Conservation Organisations of NZ Inc, an individual submitter and Waikato Domestic Beekeepers Association opposed this benefit, stating that resistance to diamides or tetraniliprole is reported in the scientific literature[1].

[1] Ralf Nauen and Denise Steinbach. Resistance to Diamide Insecticides in Lepidopteran Pests. Advances in Insect Control and Resistance Management pp 219-240 2016

6.49. Resistance to tetraniliprole will be assessed by ACVM, as such, the EPA had no information on which to assess this claimed benefit.

Lower use rates than other diamide products

6.50. The applicant claimed that Vayego would be used at lower rates than other diamide products.

6.51. The EPA noted that no supporting evidence was provided by the applicant.

6.52. Based on information from the ACVM register as of July 2019, there were three registered products using diamides (chlorantraniliprole in Altacor, chlorantraniliprole in Coragen Insecticide and chlorantraniliprole combined with abamectin in Voliam Targo). No substance containing diamide insecticide was used on grape, stone fruit or kiwifruit (since removed from the GAP table by the applicant) so no comparison could be made for these crops.

6.53. On fruit crops (pome fruits), only Altacor and Voliam Targo were used, to combat leaf rollers. Their application rate was 63 g chlorantraniliprole/ha with up to two applications per year. Therefore, Vayego had a slightly lower application rate than other diamide products per application.

6.54. Furthermore, it was noted that application rate was not indicative of lower toxicity, but would result in lower potential residue levels, therefore the level of this claimed benefit was undetermined.

Excellent crop safety

6.55. The applicant claimed that Vayego provided excellent crop safety.

6.56. Data on crop safety will be further evaluated by ACVM, as such, the EPA had no information on which to assess this benefit.

Revenue

6.57. The applicant considered the importation and use of Vayego would generate revenue for importers, transporters, retailers and spraying contractors.

6.58. The Committee considered that the availability of Vayego would provide beneficial economic effects for some businesses with the potential for flow-on effects to local communities and the New Zealand economy, including improved consumer choice and greater market competition.

Conclusion on the assessment of benefits

6.59. After considering the information that was presented, the Committee considered that there are significant benefits that will be derived for New Zealand by allowing the import or manufacture of Vayego.

7. Controls

7.1. The suite of controls proposed by the EPA include the prescribed controls triggered by the hazard classifications of Vayego, deletions and variations to the prescribed controls in accordance with section 77 of the Act, and additional controls proposed in accordance with section 77A.

Prescribed controls

7.2. The hazard classifications of Vayego determine a set of prescribed controls specified by the EPA Notices under section 77 of the Act.

7.3. The prescribed controls set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management. These controls form the basis of the controls specified in the Appendix.

7.4. The Hazardous Substances Labelling, Safety Data Sheet (SDS), Packaging, Disposal and Hazardous Property Controls (HPC) Notices Part 1, Part 3, Part 4A, Part 4B and Part 4C 2017 apply to Vayego. These controls include qualifications requirements for persons mixing, loading and applying the substance.

7.5. Clause 17 of the Labelling Notice requires that certain toxic or corrosive components are identified on the product label. Section 3 of Schedule 1 of the Safety Data Sheet (SDS) Notice requires certain toxic or corrosive components are identified on the SDS. Section 8 of Schedule 1 of the SDS Notice requires occupational exposure limits to be identified on the SDS. Several components of Vayego have a Workplace Exposure Value (WES).

Exposure limits

7.6. EPA has not set a Tolerable Exposure Limit (TEL) for Vayego, or any element or compound in the substance, as exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed.

7.7. Acceptable Daily Exposure (ADE) and Potential Daily Exposure (PDE) shown below are provided by the EPA as health-based exposure guidance values that can be used to inform risk assessments as well as the setting of controls, such as Maximum Residue Levels (MRLs) under the Agricultural Compounds and Veterinary Medicines Act 1997.

7.8. The following values have been provided for tetraniliprole:

- ADE = 0.88 mg/kg bw/day;
- PDE (food) = 0.62 mg/kg bw/day;
- PDE (drinking water) = 0.18 mg/kg bw/day;
- PDE (other) = 0.09 mg/kg bw/day.

7.9. No Environmental Exposure Limit (EEL) values are proposed at this time for tetraniliprole. This is because it is not considered that, with controls in place, environmental exposure is likely to result in an appreciable ecotoxic effect based on the quantitative risk assessment.

7.10. There are Workplace Exposure Standard (WES) values currently set for components of Vayego but, as they are not Prescribed Exposure Standard (PES) values, they are guidance values used for the management of health risk. No PES has been set for any component of Vayego.

Changes to prescribed controls

7.11. It is considered that the prescribed controls will manage most of the risks to humans and the environment. However, additional controls are recommended to be set, and default controls varied, to mitigate the non-negligible risks to the environment.

7.12. The following modifications and additions to the EPA Notice controls apply to this substance under sections 77 and 77A of the HSNO Act to manage the risks of use of Vayego.

Application rates

7.13. Significant environmental risks may occur from the use of this substance, due to the hazards posed by tetraniliprole, the active ingredient in Vayego. Therefore, it is considered necessary to set a maximum application rate, number of applications and frequency.

7.14. The maximum application rate on pome fruits is set to be 0.3 L/ha (equivalent to 60 g of tetraniliprole) with two applications per calendar year, with a minimum interval of 21 days between applications.

7.15. The maximum application rate on stone fruits is set to be 0.3 L/ha (equivalent to 60 g of tetraniliprole) with two applications per calendar year, with a minimum interval of 14 days between applications.

7.16. The maximum application rate on grapes is set to be 0.3 L/ha (equivalent to 60 g of tetraniliprole) with one application per calendar year.

Application methods

7.17. The environmental risk assessment was based on the application method (airblast) specified by the applicant. In particular, the application with ground-based methods and to favourable wind conditions are key factors in minimising exposure to aquatic environments from spray drift.

7.18. Vayego must only be applied by ground-based methods.

7.19. Vayego must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.

Application restriction

7.20. Vayego can only be applied post-bloom.

Buffer zones

7.21. The person in charge of the application of this substance and any person applying this substance must ensure that the substance is not applied within a specified distance of a waterbody.

7.22. For this substance the following buffer zones apply (Table 3), according to the relevant application method and scenario:

- When applied twice on pome fruit, Vayego must not be applied within 25 m of any waterbody;
- When applied twice on stone fruit, Vayego must not be applied within 25 m of any waterbody;
- When applied once on grape, Vayego must not be applied within 20 m of any waterbody and within 10 m of a downwind waterbody.

Table 3: Required buffer zones for Vayego

Application method	Sensitive area	Required buffer zone (m)
Ground-based Pome fruit	Waterbody	25
	Waterbody (downwind)	25
Ground-based Stone fruit	Waterbody	25
	Waterbody (downwind)	25
Ground-based Grapes	Waterbody	20
	Waterbody (downwind)	10

Labelling

7.23. An additional label statement to support mitigation measures is proposed when two applications per year are planned (or words to the same effect):

- "The best available application technique, which minimises off-target drift should be used to reduce effects on non-target insects or other arthropods."

Review of additional controls and variations

7.24. The full suite of controls, including variations, can be found in Appendix A of this document.

7.25. At the hearing, the applicant was given an opportunity to comment on the proposed controls as set out in the Staff Report. The applicant initially had concerns regarding the size of the buffer zone controls. After receiving additional information from the applicant following the Direction and Minute (issued 21 November 2019), the EPA revised the buffer zones and published the revised buffer zones in an addendum to the risk assessment (issued 12 March 2020), giving the applicant ten days to comment.

7.26. The applicant had further concerns regarding the wording of the controls in the previous Staff Report (published September 2019). In particular, both the application rate control and the buffer zone control

were linked to the intended crop not the application rate and application method. The applicant's preference was to have set the maximum application rate to be independent of the crop, and to link the buffer zone control to the application method.

7.27. The Committee acknowledged the changes to the buffer zones in the addendum to the risk assessment, and the comments received from the applicant, and agreed with the controls recommended by the EPA.

7.28. The Committee reviewed the additional controls and variations to the prescribed controls mentioned above and considered them necessary to achieve their purpose of effective risk management of the use of Vayego in New Zealand.

8. Conclusion

8.1. After taking into account the assessment of potential risks and benefits associated with Vayego, the Committee considered that, with the prescribed controls and additional controls in place:

- the overall risks to human health and the environment arising from the hazardous properties and the use of Vayego will be negligible;
- significant adverse effects on the social or economic environment or international obligations from the use of Vayego are not anticipated;
- if Vayego is applied in the proposed manner, it would likely be consistent with the principles of Te Tiriti o Waitangi (the Treaty of Waitangi). Significant adverse effects on the relationship of Māori and their culture and traditions with their environment and taonga, including culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga have not been identified.
- Benefits will be derived for New Zealand by allowing the use of Vayego.

8.2. The Committee noted that the EPA did not recommend the use of an EC_{10} for the risk assessment at this point in time but agreed that it would be prudent to carefully explore this option and change the methodology, if needed, in the future. The Committee noted that similar comments applied to other aspects of the risk assessment methodology such as those noted by the applicant in relation to spray drift. The Committee recommends that the EPA investigate such options.

9. Decision

9.1. Pursuant to section 29 of the Act, the Committee has considered this application for approval under section 28 of the Act. The Committee has considered the effects of this substance throughout its life cycle, the controls that may be imposed on this substance and the likely effects of this substance being unavailable. The Committee has also taken into account the considerations set out in Part 2 of the Act.

9.2. The Committee considered that, with controls in place, the risks to human health and to the environment will be negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, the application to import or manufacture Vayego for release is approved with controls in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998.

Environmental Protection Authority
Te Mana Rauhī Taiao

Signed: Dr Kerry Laing	**Date: 26 May 2020**
Chair, Decision Making Committee, Environmental Protection Authority	

Appendix: Controls applying to Vayego

EPA Controls

Control code	Notice	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of class 9 pesticides

HSNO Additional Controls and Modifications to Controls

<table>
<tr><th>Code</th><th>HSNO Act</th><th>Control</th></tr>
<tr><td>Application rate</td><td>Section 77 variation to HPC Notice clause 50</td><td>The maximum application rate on pome fruits is set to be 0.3 L/ha (equivalent to 60 g of tetraniliprole) with two applications per calendar year, with a minimum interval of 21 days between applications.

The maximum application rate on stone fruits is set to be 0.3 L/ha (equivalent to 60 g of tetraniliprole) with two applications per calendar year, with a minimum interval of 14 days between applications.

The maximum application rate on grape is set to be 0.3 L/ha (equivalent to 60 g of tetraniliprole) with one application per calendar year.</td></tr>
<tr><td>Application method</td><td>Section 77A</td><td>The substance must only be applied by ground-based methods.

The substance must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.</td></tr>
<tr><td>Application restriction</td><td>Section 77A</td><td>The substance can only be applied post-bloom.</td></tr>
<tr><td>Buffer zone</td><td>Section 77 variation to HPC notice clause 51</td><td>The person in charge of the application of this substance and any person applying this substance must ensure that the substance is not applied within a specified distance of a waterbody.

For this substance the following buffer zones apply, according to the relevant application method and scenario:
<table>
<tr><th>Application method</th><th>Sensitive area</th><th>Required buffer zone (m)</th></tr>
<tr><td rowspan="2">Ground-based Pome fruit</td><td>Waterbody</td><td>25</td></tr>
<tr><td>Waterbody (downwind)</td><td>25</td></tr>
<tr><td rowspan="2">Ground-based Stone fruit</td><td>Waterbody</td><td>25</td></tr>
<tr><td>Waterbody (downwind)</td><td>25</td></tr>
<tr><td rowspan="2">Ground-based grapes</td><td>Waterbody</td><td>20</td></tr>
<tr><td>Waterbody (downwind)</td><td>10</td></tr>
</table></td></tr>
<tr><td>Label</td><td>Section 77

Variation to Labelling Notice</td><td>The substance label must include the following statement, or words to the same effect:
The best available application technique, which minimises off-target drift should be used to reduce effects on non-target insects or other arthropods.</td></tr>
</table>

HSW HS Requirements

Note: these requirements are triggered by the ecotoxic properties of Vayego and apply under the HSNO Act and the EPA Hazardous Property Controls (HPC) Notice.

Code	Regulation	Description	Extra information
HSW2-1	Reg 2.1	Workplace labelling of hazardous substance containers	See clause 37 of the HPC Notice
HSW2-2	Reg 2.5 - 2.10	Signage	See clause 43 of the HPC Notice
HSW2-3	Reg 2.11	Safety data sheets	See clause 38 of the HPC Notice
HSW5-2	Reg 5.6 - 5.12	Emergency response plans	See clause 42 of the HPC Notice
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate	See clause 47 of the HPC Notice
HSW13-14	Reg 13.30	Secondary containment requirements for class 6 and 8 pooling substances	See clause 41 of the HPC Notice
HSW17-1	Part 17	Requirements for surface containers	See clause 39 of the HPC Notice

Definitions

Terms used in the controls have the same meaning as defined in the Act, EPA Notices or regulations made under the Act. In addition, the following definitions apply:

Term	Definition
ai	Active ingredient - the biologically active chemical in a pesticide product
Downwind	Downwind refers to a location in a direction to where the wind blows away from the application area
EC_{10}	Effective Concentration at which an observable adverse effect is caused in 10% of the test organisms
EC_x	Effective Concentration at which an observable adverse effect is caused in x% of the test organisms
GAP	Good Agricultural Practice
Ground-based application	Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, airblast or knapsack, and do not include aerial application methods
In-field	Inside the area treated with a substance
Likely	Good chance that it may occur under normal operating conditions
NOEC	No Observed Effect Concentration – being the highest concentration of a substance that does not produce a significant ecotoxic effect in an organism or in an organism population
Off-field	Outside the area treated with a substance

Waterbody	Includes all natural and modified/artificial water courses such as reservoirs, irrigation canals, water-supply races, canals for the supply of water for electricity generation or farm drainage, ditches, streams, rivers, ponds and lakes. For clarity, it excludes fully covered pipes, tanks or other enclosed structures, puddles or groundwater

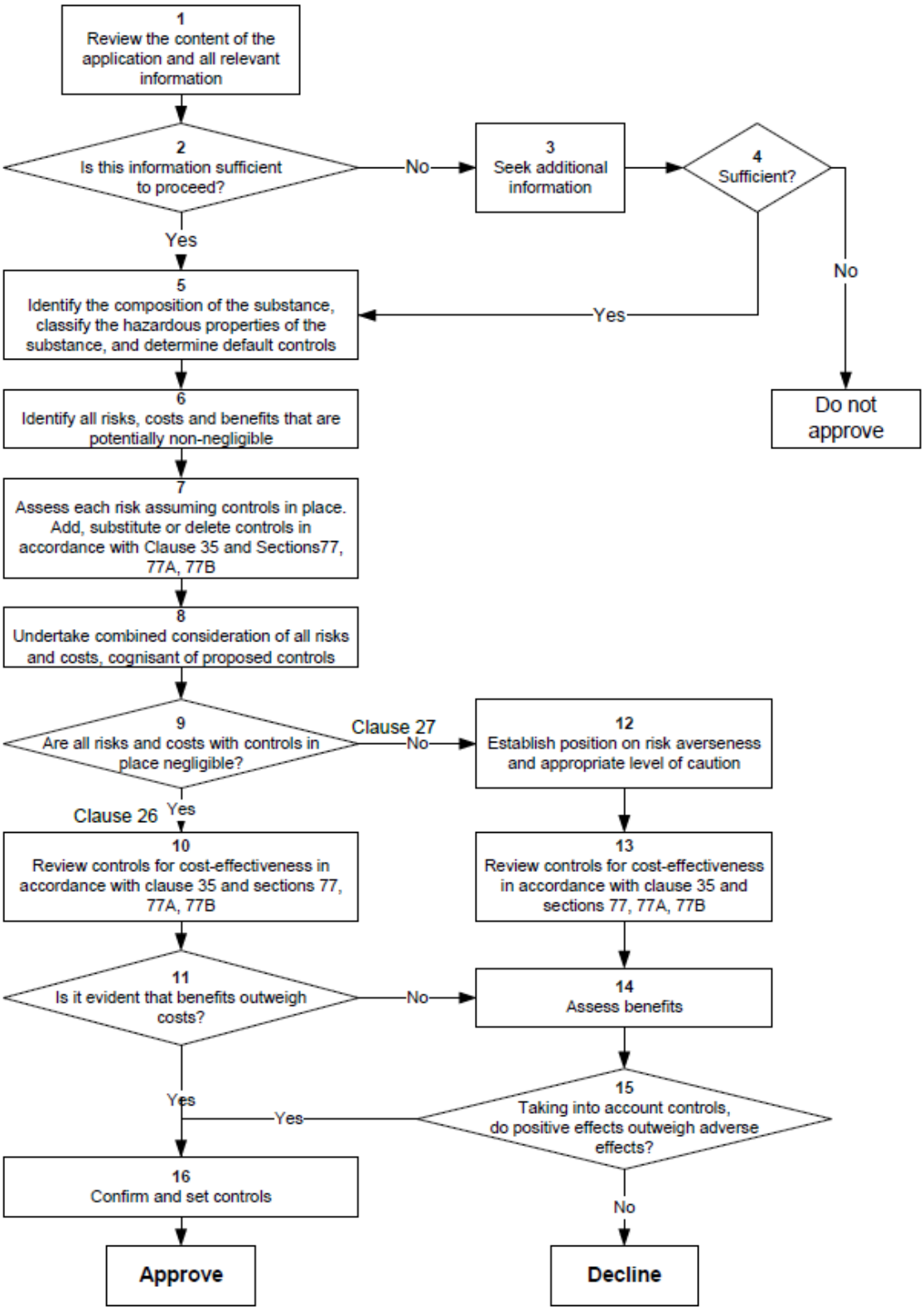
Appendix B: Decision Path

Context

This decision path describes the decision-making process for applications to import or manufacture a hazardous substance. These applications are made under section 28 of the HSNO Act and determined under section 29.

Decision path for applications to import or manufacture a hazardous substance, application made under section 28 of the Act and determined under section 29.

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.



Explanatory Notes

Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision. The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.
Item 3:	**(If 'no' from item 2) Seek additional information** If there is not sufficient information then additional information may need to be sought from the applicant, EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).
Item 4	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).
Item 5:	**(If 'yes' from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls** Identify the composition of the substance, and establish the hazard classifications for the identified substance. Determine the default controls for the specified hazardous properties using the regulations "toolbox".
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible[2]** Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these „values" are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as "sunk" costs (see footnote 2). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11). Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).

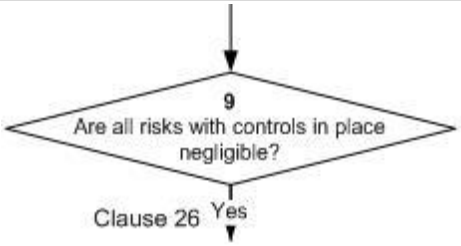
[2] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called "sunk" costs since they are incurred whether or not the application is successful.

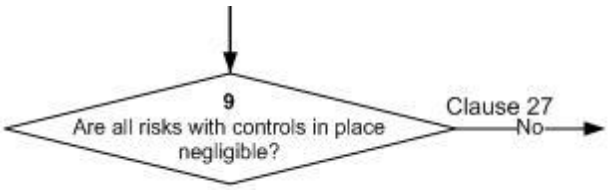
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[3]. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)). Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14). Consider short term and long term effects. Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.
	Step 2:	Document those risks, costs and benefits that can be readily concluded to be negligible[4], and eliminate them from further consideration. Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.
Item 7:		**Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.** The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place. Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of its occurring. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account. The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost. This assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)). Consider the HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls. See EPA report 'Approach to Risk' for further guidance[5].

[3] Effects on the natural environment, effects on human health and safety, effects on Maori culture and traditions, effects on society and community, effects on the market economy.

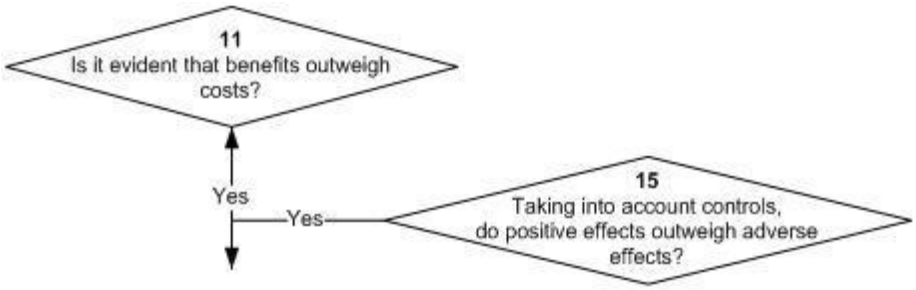
[4] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits".

[5] http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

	Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 10 and 13. If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.
Item 8:	**Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a „basket" of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.
Item 9:	**Are all risks with controls in place negligible?** Looking at individual risks in the context of the "basket" of risks, consider whether all of the residual risks are negligible.
Item 10:	 **(From item 9 - if 'yes') Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** Where all risks are negligible the decision must be made under clause 26 of the Methodology. Consider the practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.
Item 11:	**Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of

	internal or private net benefit, and therefore total benefits outweigh total costs[6]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs. However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 14).
Item 12:	 **(If 'no' from item 9) Establish position on risk averseness and appropriate level of caution** Although "risk averseness" (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).
Item 13:	**Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9 and 12). Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result. As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.
Item 14:	**(If 'no' from item 11 or in sequence from item 13) Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect.

[6] Technical Guide "Decision making" section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs. See also Protocol Series 1 "General requirements for the Identification and Assessment of Risks, Costs, and Benefits".

	An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[7]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs. As for risks and costs, the assessment is carried out with the default controls in place.
Item 15:	**Taking into account controls, do positive effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13. Where this item is taken in sequence from items 12, 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.
Item 16:	 **(If 'yes' from items 11 or 15) Confirm and set controls** Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

[7] This principle derives from Protocol Series 1, and is restated in the Technical Guide "Decision making".